**EXPLANATORY STATEMENT**

**INSTRUMENT NUMBER PB 88 OF 2020**

***NATIONAL HEALTH ACT 1953***

***National Health (Weighted average disclosed price – October 2020 reduction day)
Amendment Determination 2020***

**Authority**

This legislative instrument is made pursuant to subsection 99ADB(4) of the *National Health Act 1953* (the Act), which provides that the Minister may, by legislative instrument, determine the weighted average disclosed price (WADP) of a brand of a pharmaceutical item (listed brand) in accordance with the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations).

Subsection 99ADB(7) of the Act further provides that a subsection 99ADB(4) determination for a listed brand may include the adjusted approved ex-manufacturer price (AAEMP) for the listed brand.

**Purpose**

This legislative instrument amends the *National Health (Weighted average disclosed price – October 2020 reduction day) Determination 2020* (PB 54 of 2020) (the Principal Instrument) by:

* amending the WADPs for brands of the pharmaceutical item:
	+ Zoledronic acid, Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL, injection (zoledronic acid);
* removing from Schedule 1 and inserting in Schedule 2 WADPs for brands of pharmaceutical items containing:
	+ Epirubicin injection/intravesical (epirubicin);
	+ Etoposide injection (etoposide);
* inserting WADPs for brands of pharmaceutical items that moved to the F2 formulary after publication of the Principle Instrument:
	+ - Levodopa with carbidopa and entacapone oral:
			* Tablet 100 mg-25 mg as monohydrate-200 mg
			* Tablet 150 mg-37.5 mg as monohydrate-200 mg
			* Tablet 50 mg-12.5 mg as monohydrate-200 mg
			* Tablet 125 mg-1.25 mg as monohydrate-200 mg
			* Tablet 200 mg-50 mg as monohydrate-200 mg
			* Tablet 75 mg-18.75 mg as monohydrate-200 mg
		- Lurasidone oral:
			* Tablet containing lurasidone hydrochloride 40 mg
			* Tablet containing lurasidone hydrochloride 80 mg
		- Metformin oral, tablet (prolonged release) containing metformin hydrochloride 500 mg
		- Methylphenidate oral, capsule containing methylphenidate hydrochloride 60 mg modified release
		- Nitrofurantoin oral:
			* Capsule 100 mg
			* Capsule 50 mg
		- Salbutamol inhalation by mouth, pressurised inhalation 100 micrograms (as sulfate) per dose with dose counter, 200 doses (CFC-free formulation).

The Principal Instrument was made pursuant to subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act for brands of pharmaceutical items with a data collection period ending 31 March 2020 (2020 October cycle).

**Amendments**

*Revision of WADP determinations for Brands of Pharmaceutical Items*

Amendments are being made following consideration of matters raised by responsible persons concerning the determinations in the Principal Instrument for brands of pharmaceutical items containing zoledronic acid, epirubicin and etoposide.

A review of determinations in response to matters raised by responsible persons revealed that:

* A responsible person for zoledronic acid had submitted incorrect data. Corrected data was submitted. New calculations for the WADPs set out in this amending determination were completed in accordance with the Act and Regulations;
* Etoposide has an exemption from the Pharmaceutical Benefits Advisory Committee (PBAC) for price disclosure reductions, moving the drug from Schedule 1 to Schedule 2; and
* Epirubicin will not take a reduction due to the correct threshold for its calculations being 30 per cent, moving the drug from Schedule 1 to Schedule 2.

*Insertion of WADP determinations for New Brands of New Pharmaceutical Items*

WADPs do need to be determined for new brands listing between 31 March 2020 and 1 October 2020 that have no other existing brand of the same pharmaceutical item. Examples are s19A temporary listings (imipramine and metformin), drugs that moved from F1 or the administrative combination drugs list to F2 (levodopa with carbidopa and entacapone, lurasidone and nitrofurantoin) and new strengths or forms of drugs (salbutamol and methylphenidate).

There are 27 brands of 14 new pharmaceutical items that are included in this amending instrument, as follows:

* Imipramine (Leading) brand of imipramine oral, tablet containing imipramine hydrochloride 25 mg USP
* Levodopa with carbidopa and entacapone oral:
	+ Tablet 100 mg-25 mg as monohydrate-200 mg: Lecteva and Stalevo brands
	+ Tablet 150 mg-37.5 mg as monohydrate-200 mg: Lecteva and Stalevo brands
	+ Tablet 50 mg-12.5 mg as monohydrate-200 mg: Lecteva and Stalevo brands
	+ Tablet 125 mg-1.25 mg as monohydrate-200 mg: Lecteva and Stalevo brands
	+ Tablet 200 mg-50 mg as monohydrate-200 mg: Lecteva and Stalevo brands
	+ Tablet 75 mg-18.75 mg as monohydrate-200 mg: Lecteva and Stalevo brands
* Lurasidone oral:
	+ Tablet containing lurasidone hydrochloride 40 mg: Latuda, Lurasidone Lupin and Ardix Lurasidone brands
	+ Tablet containing lurasidone hydrochloride 80 mg: Latuda, Lurasidone Lupin and Ardix Lurasidone brands
* Metformin (Medsurge) brand of metformin oral, tablet prolonged release containing metformin hydrochloride 500 mg
* Ritalin LA brand of methylphenidate oral, capsule containing methylphenidate hydrochloride 60 mg modified release
* Nitrofurantoin oral:
	+ Capsule 100 mg: APO-Nitrofurantoin and Macrodantin brands
	+ Capsule 50 mg: APO-Nitrofurantoin and Macrodantin brands
* Ventolin CFC-Free with dose counter and Zempreon CFC-Free with dose counter brands of salbutamol inhalation by mouth, pressurised inhalation 100 micrograms as sulfate per dose with dose counter 200 doses CFC free formulation.

 *Basis for amendments*

Subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to vary or revoke the determination made under subsection 99ADB(4) for the medicines affected by this amending instrument.

**Consultation**

This instrument affects companies that are responsible persons for all brands of all pharmaceutical items containing zoledronic acid, epirubicin and etoposide.

All of the affected responsible persons were consulted about the amendments. While some responsible persons requested clarification of the impact of this instrument, all concerns raised have been addressed. No additional consultation with experts was undertaken, as consultation with affected responsible persons drew on the knowledge of persons with relevant expertise.

This instrument commences on the day after it is registered on the Federal Register of Legislation. This instrument is a legislative instrument for the purposes of the *Legislation Act 2003.*

**Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

***National Health (Weighted average disclosed price – October 2020 reduction day)
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This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Overview of the Legislative Instrument**

This instrument amends the *National Health (Weighted average disclosed price – October 2020 reduction day) Determination 2020* (the Principal Instrument) to: a) amend prices of brands of pharmaceutical items which continue to have a price reduction on reduction day, b) remove brands of pharmaceutical items which will no longer have a price reduction on reduction day, and c) insert prices for new brands of new pharmaceutical items.

Part VII of the Act is the legislative basis for the Pharmaceutical Benefits Scheme (PBS) by which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

Part VII, Division 3B of the Act deals with price disclosure. Price disclosure provides for the ‘approved ex-manufacturer price’ of a ‘brand of a pharmaceutical item’ to be reduced on a reduction day in certain specified circumstances. The reduction is based on sales revenue, incentives and volume data collected from Responsible Persons (drug companies) and occurs in accordance with the Act and the Regulations.

The amendments are made to provide for correct and effective reductions in prices for pharmaceutical benefits on 1 October 2020 under the statutory provisions for price disclosure.

**Human rights implications**

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines.

The price disclosure program progressively reduces the price of some PBS medicines which are subject to competition, ensuring better value for money from these medicines. These reductions may also result in patients accessing these medicines at lower prices.

**Conclusion**

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

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